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(H)

APPLICATION NO. 62	FILING DATE 97	FIRST NAMED INVENTOR VAN ARSDELL	ATTORNEY DOCKET NO. 04599/005001
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EXAMINER
TUNG, P.

ART UNIT 1632 PAPER NUMBER 12

DATE MAILED: 02/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/914,332	Applicant(s) Van Arsdell et al.
	Examiner Peter Tung	Group Art Unit 1652



Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-31 is/are pending in the application.

Of the above, claim(s) 23-31 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-22 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-22 in Paper No. 10 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3, 5-9 and 11-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term "lysine analog" in claims 1, 5, 6, 9 and 15-18 is a relative term which renders the claim indefinite. The term "lysine analog" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For the purpose of this Office action, "lysine analog" is understood to be a compound structurally similar to lysine that can serve as an amino donor for a DAPA aminotransferase (Specification, page 7, lines 14-16).

5. The term "analog of SAM" in claim 14 is a relative term which renders the claim indefinite. The term "analog of SAM" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

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not be reasonably apprised of the scope of the invention. For the purpose of this Office action, "analog of SAM" is understood to be a compound structurally similar to SAM which can serve as an amino donor for DAPA aminotransferase (Specification, page 7, lines 3-8).

6. Claims 3, 7, 8, 11-13 and 19-22 are indefinite because they depend upon an indefinite base claim and fail to correct the problem.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The bacterium comprising the lysine-utilizing DAPA aminotransferase, strain BI282, disclosed on page 113, lines 28-30 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. *See 37 CFR 1.808.* Further, the record must be clear

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that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met. Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

9. Claims 1, 3 and 5-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a biotin vitamer by culturing a bacterium comprising a lysine-utilizing DAPA aminotransferase in an environment enriched for lysine or a lysine analog , does not reasonably provide enablement for a method of producing a biotin vitamer by culturing said bacterium in an environment enriched for a lysine precursor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented and (3) the presence or absence of

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working examples. A large amount of experimentation would be required to identify all suitable lysine precursors. As the purpose of adding a lysine precursor is to provide an amino donor to the DAPA aminotransferase of the bacterium, much experimentation would be required to determine which precursors can function as amino donors for the enzyme. No guidance is provided on which lysine precursors can function as amino donors. Guidance is required to help determine which lysine precursors to use with the bacterium in order to produce biotin vitamers. No working examples of lysine precursors are provided which function as DAPA aminotransferase amino donors. Examples of lysine precursors which function as DAPA aminotransferase amino donors would allow the use of the precursor in making biotin vitamers and would provide guidance on other precursors which can function as amino donors and be used in producing biotin vitamers in bacteria.

10. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented and (3) the presence or absence of working examples. A large amount of experimentation would be required to determine how to deregulate one of the biotin biosynthetic pathways as deregulation would involve promoter, operator and

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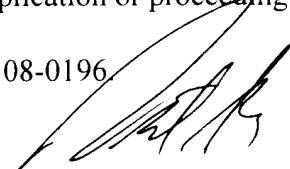
repressor sequences for each of the steps of biotin biosynthesis besides the *bioA* gene. No guidance is provided on how to obtain a bacterium which is deregulated in at least one biotin synthetic pathway step other than *bioA* expression. Guidance on what is required to deregulate one of the synthetic pathways would allow one of skill in the art to make such a bacterium. No examples are provided of bacteria with a deregulated biotin synthetic pathway other than *bioA* expression. Examples of such bacteria would allow a person of skill in the art to make other deregulated pathway bacteria. Examples would provide guidance on how deregulation of the pathway could be accomplished.

Allowable Subject Matter

11. Claims 1-22 are allowable over the prior art of record.
12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (703) 308-4216. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Robert A. Wax
Supervisory Patent Examiner
Technology Center 1600